

DEPARTMENT OF THE NAVY HEADQUARTERS, UNITED STATES MARINE CORPS WASHINGTON, DC 20380-1775

NORMAL

TI 4733-35/24 31 October 2000

U. S. MARINE CORPS TECHNICAL INSTRUCTION

UNITED STATES MARINE CORPS METROLOGY CALIBRATION QUALITY PROGRAM

Encl: (1) Quality Program Manual dated 29 September 2000

- **1.** <u>Purpose.</u> To provide documented instructions and procedures of the calibration quality program for the Marine Corps as required by TI 4733-35/23 and ANSI/NCSL Z-540-1 (1994).
- 2. <u>Information.</u> The enclosed Quality Manual describes the Quality Assurance Program and procedures used in Marine Corps Calibration Laboratories. The measurement objectives are:
- a. Maintain and disseminate accurate units of measurements, which are technically adequate to support Marine Corps calibration laboratories and fleet Test and Measuring Systems (TAMS).
 - b. Provide reliable and responsive calibration measurement services suited to the needs of our customers.
- c. Ensure all calibration laboratory standards are traceable to National or International Standards through the Marine Corps Measurement Transfer Standards Program, Navy Primary Standards Laboratory (NPSL) and other certified primary standards laboratories.

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TI 4733-35/24

3. Action. Marine Corps calibration laboratories and activities will use the enclosure as required to achieve the quality assurances required by the Program Manager, Test, Measurement, and Diagnostic Equipment (TMDE) for all Marine Corps TMDE.

BY DIRECTION OF THE COMMANDANT OF THE MARINE CORPS

OFFICIAL

J. A. BRYANT

Acting Director, Technical Data Management Division Marine Corps Logistics Bases

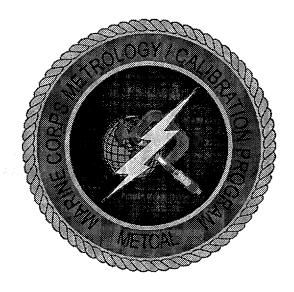
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Marine Corps METCAL Quality Program Manual

29 SEPTEMBER 2000



UNCONTROLLED COPY

Prepared by Marine Corps Systems Command Quality Program Manager, TMDE

Of the Marine Corps METCAL Quality Program Manual

As the Program Manager, Test Measurement and Diagnostic Equipment and having responsibility for policy, guidance, and technical direction for the Marine Corps Test Measurement and Diagnostic Equipment Calibration And Maintenance Program, I have reviewed and endorsed the Marine Corps METCAL Quality Program Manual and approve its use in the operation and management of Marine Corps Ground Calibration Facilities.

LtCol Marie Juliano

Program Manager, TMDE

Marine Corps Systems Command

FOREWORD

The Chief of Naval Operations and the Commandant of the Marine Corps have adopted the American National Standard for Calibration - ANSI/NCSL Z-540-1 (1994) - Calibration Laboratories and Measuring and Test Equipment - General Requirements, approved by the American National Standards Institute (ANSI) and published by the National Conference of Standards Laboratories (NCSL), as the primary basis for criteria to ensure Naval and Marine Corps Calibration Laboratories are capable of performing required calibration measurements. The Department of the Navy has been granted authority to use, in its entirety, the ANSI/NCSL Z-540-1 (1994) for the purpose of improving quality within the Navy and Marine Corps Calibration Program as a result, TI-4733-35/23 Naval and Marine Corps Calibration Laboratory Audit / Certification Manual was developed and directed for use on 9 Mar 1998.

Marine Corps fleet ground calibration laboratories and activities are established, equipped, staffed and authorized to calibrate to measurement accuracy levels necessary to meet mission requirements. MARCORSYSCOM Metrology and Calibration (METCAL) program directs up front metrology engineering analysis to determine calibration support plans for all platforms, weapon systems and end test items. These metrology engineering studies result in the selection and procurement of calibration standards and the development of instrument calibration procedures; providing all Marine Corps calibration activities with pre-engineered parametric capabilities traceable to the Navy Primary Standards Laboratory (NPSL), National Institute of Standards and Technology (NIST), U.S. Naval Observatory, or other Marine Corps approved sources.

TI-4733-35/23_ and ANSI/NCSL Z-540-1 (1994) standards require that a calibration laboratory develop and maintain a Quality Program that is documented in a Quality Manual. A Quality Program is defined as "the organizational structure, responsibilities, procedures, processes and resources for implementing quality management". A Quality Manual is defined as "a document stating the quality policy, Quality Program, and quality practices of an organization". The Quality Manual may reference other laboratory documentation.

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1 Scope

1.1 Objective and Applicability

This Quality Manual describes the Quality Assurance Program and procedures used in Marine Corps Calibration Laboratories. It sets forth established requirements to achieve the Quality Assurance Program objectives of MARCORSYSCOM's METCAL program, directed by the Program Manager, Test, Measurement, and Diagnostic Equipment (PM TMDE). The measurement objectives are:

- 1.1.1 Maintain and disseminate accurate units of measurements, which are technically adequate to support Marine Corps calibration laboratories and fleet Test and Measuring Systems (TAMS).
- 1.1.2 Provide reliable and responsive calibration measurement services suited to the needs of our customers.
- 1.1.3 Ensure all calibration laboratory standards are traceable to the NPSL, NIST, U.S. Naval Observatory, or other Marine Corps approved sources.

1.2 Parameters

- 1.2.1 Marine Corps calibration laboratories and activities are established, equipped, staffed, and authorized to calibrate to measurement accuracy levels necessary to meet mission requirements. Measurement capabilities for this laboratory are located in the laboratory's Turnover Folder. The METCAL program directs up-front metrology engineering analysis to determine calibration support plans for all weapon systems and test end items. These metrology-engineering studies result in the selection/procurement of calibration standards and the development of instrument calibration procedures. These studies also provide all Marine Corps calibration activities with pre-engineered parametric capabilities traceable to the NPSL, NIST, U.S. Naval Observatory, or other Marine Corps approved sources.
- 1.2.2 This laboratory Quality Manual is based on TI-4733-35/23_ and the American National Standard ANSI/NCSL Z-540-1 (1994) Calibration Laboratories and Measuring and Test Equipment General Requirements, and is used in conjunction with reference documents identified within this quality manual.

2 References

References described in this Quality Manual are available via the PM TMDE web site or maintained on file in the calibration laboratory and are accessible to all laboratory personnel. It is the user's responsibility to use the most current revision.

2.1 Marine Corps / Navy References

2.1.1 **SECNAVINST 3960.6** – Navy Metrology and Calibration Program

- 2.1.2 MCO P4790.2 MIMMS Field Procedures Manual
- 2.1.3 **MCO** 4733.1_ Marine Corps Test, Measurement, and Diagnostic Equipment (TMDE) Calibration and Maintenance Program (CAMP).
- 2.1.4 **MCO 10510.18**_ Policy and Responsibility for Electronics Test and Measuring Equipment.
- 2.1.5 **TI-4733-35/23** Naval and Marine Corps Calibration Laboratory Audit / Certification Manual.
- 2.1.6 **TI-4733 Series** Procedural aspects, Marine Corps Test, Measurement, and Diagnostic Equipment (TMDE) Calibration and Maintenance Program (CAMP). List of Technical Instruction's (TI's) are located in TI-4733-15/7C.
- 2.1.7 **TM 09635-15/1** Calibration Facility AN/TSM-198.
- 2.1.8 TI-4733-15/13 Metrology Requirements List.
- 2.1.9 DoD MIDAS Metrology Information and Documentation Automation System.
- 2.1.10 NA 17-35FR06 Calibration Facility Requirements.
- 2.1.11 NA 17-20 Series Instrument Calibration Procedures (ICPs).

2.2 Laboratory References

- 2.2.1 Turnover folder A folder maintained by the Calibration Officer/Chief that contains documentation defining laboratory operations. In addition to content outlined in MCO P4790.2_, the following items are included:
 - a. List of Measurement Capabilities
 - b. Organizational chart
 - c. Job assignments
 - d. Job descriptions
 - e. Authorization list of personnel verifying; Labmate data entries, signing Calibration Certificates and Reports of Calibration
 - f. Laboratory layout diagram (see section 7.1.2)
 - g. List of customers
 - h. Description of Internal Quality Verification Inspection random sampling process.
 - i. Documentation supporting deviations from the Quality Manual, will meet the intent of TI-4733-35/23 and be approved by the QPM.

2.2.2 Desktop Procedures – A list of specific procedures, references and points of contact and other significant information concerning the duties of a particular billet. The personnel assigned to the billet maintain desktop procedures per MCO P4790.2_.

2.3 National / International References

NOTE: This Quality Manual was written using the references listed in this section. The core of this manual was written following the criteria of ANSI/NCSL Z540-1 (1994); with amplified guidance using Marine Corps METCAL Program support elements to develop and promote a specific Quality Assurance Program for calibration laboratories.

- 2.3.1 **ANSI/NCSL Z540-1**: 1994 American National Standard for Calibration Calibration Laboratories and Measuring and Test Equipment General Requirements. Note: This reference is included in the TI-4733-35/23_.
- 2.3.2 **ISO 9002**: 1994 Quality Systems Model for Quality Assurance. Note: This reference and supporting documentation is applicable to Depot Calibration Laboratories only.

3 Quality Policy and Document Control

3.1 Quality Policy Statement

This calibration laboratory commits to excel at our principal product and diverse support; providing our customers the highest quality of calibration services at the best value to maintain the highest state of combat mission readiness.

3.2 Accomplishment

We will accomplish our objective, as indicated in the Policy Statement by staying abreast of advancing technology, collaborating with suppliers, customers and other calibration laboratories in applying continuous process improvement to our laboratory Quality Program and operations.

3.3 Commitment

The PM TMDE, Assistant Program Manager for Calibration and TMDE Management Systems (APM CTMS) and Quality Program Manager (QPM) of MARCORSYSCOM, Calibration Officer/Chief, Section Heads, Quality Assurance Representative (QAR) and all other calibration laboratory personnel are committed to this Quality Policy Statement.

3.3.1 **Tests**: The laboratory conducts tests and performs calibrations of test items in accordance with (IAW) approved step-by-step Instrument Calibration Procedures (ICPs); under conditions required by the Marine Corps METCAL Program (see referenced documents contained in Section 2 of this manual). The techniques utilized

for specific tests ensure the accuracy, tolerance, precision, repeatability, traceability and uncertainty required for the tests are within the applicable METCAL program guidelines.

3.3.2 **Independence**: PM TMDE, to and including inter-laboratory management (Calibration Officer/Chief and Section Heads) ensure that the laboratory is independent from any commercial, financial, or other pressures which might adversely affect the quality of tests and resulting reports.

3.4 **Document Control**

- 3.4.1 The authorized "read only" version of this document is the only controlled copy and is maintained as an Adobe Acrobat (PDF) file on the Marine Corps' PM-TMDE web site at https://iis.marcorsyscom.usmc.mil/PMTMDE. The web site requires a password. It is the user's responsibility to ensure that printed copies of this and any other document utilized in fulfilling the requirement of the quality standard are the current version. The current version of the Quality Manual is verified by the date of the printed copy to that of the authorized version on the web site.
- 3.4.2 The QPM has the authority to modify/update the Quality Manual. The Quality Manual is annually reviewed, and updated if required. PM TMDE is responsible for final approval of the Quality Manual and subsequent revisions. After approval, PM TMDE directs the loading of the revised document to the Marine Corps' PM-TMDE web site. https://iis.marcorsyscom.usmc.mil/PMTMDE. The QPM maintains the electronic file of the revised Quality Manual.
- 3.4.3 This Quality Manual (along with associated appendices and references) is available to all laboratory personnel. The Calibration Officer/Chief has overall responsibility for the Quality Program within the laboratory. The Section Heads are responsible for ensuring that all personnel familiarize themselves and comply with the policies and procedures established in the manual and associated documentation.
- 3.4.4 In extreme cases, when the laboratory must deviate from this Quality Manual. Deviations will meet the intent of TI-4733-35/23, be approved by the QPM and supporting documentation will be included in the Turnover Folder. Usually these are rare instances and may be included in the next revision of the Quality Manual.

4 Organizational and Management

4.1 Legal Status

SECNAVINST 3960.6 directs the Marine Corps to establish and maintain a Calibration Program. MCO 4733.1_ assigns the responsibility of policy, guidance and technical direction of Marine Corps TMDE CAMP to COMMARCORSYSCOM, PM TMDE. PM TMDE equipped, and authorized Marine Corps Calibration Laboratories identified in MCO 4733.1B to perform calibration of standards and Test and Measuring Systems at accuracy levels necessary to meet our assigned mission.

4.2 Organization and Management

- 4.2.1 PM TMDE provides program policy; required standards; metrology engineering, logistics support and funding resources for calibration support and services to Marine Corps Fleet customers. The organizational structure for the quality assurance program includes PM TMDE, APM CTMS, QPM and the QAR. Other key staff positions within the laboratory are; the Calibration Officer/Chief and Section Heads.
- 4.2.2 The QPM's role in the quality program is to provide the necessary assistance to the Marine Corps calibration laboratories to meet the requirements set forth by the TI-4733-35/23_. Scheduled activities include; Quality personnel training, assist with implementation of new quality processes, conduct and oversee laboratory audits, assist in the correction of any non-conformances, identify areas of concern and make recommendations. The QPM continually interrelates with each calibration laboratory to provide assistance, and collect quality data and information. This reduces duplicate efforts between the laboratories, and provides a greater scope of analysis to base decisions for continuous improvement in the quality program and optimizes the efficiency of the laboratory quality personnel.
- 4.2.3 Job descriptions for all laboratory positions are defined in this section, in the laboratory's turnover folder, or desktop procedures maintained in the laboratory.
- 4.2.4 A block diagram laboratory organizational chart is located in the laboratory's turnover folder, which depicts the organization and management structure of the laboratory.

4.3 Key Staff Responsibilities within the Laboratory

- 4.3.1 The **Calibration Officer / Chief** is responsible for overall compliance to this Quality Manual and the management of the laboratory: The Calibration Officer/Chief is also responsible for the following:
- 4.3.1.1 Implements and enforces applicable good laboratory practices described in reference documents.
- 4.3.1.2 Provides resources, adjusts workloads, and provides training opportunities for laboratory staff to facilitate completion of assigned tasks in a safe work environment consistent with test requirements and personnel capabilities.
- 4.3.1.3 Assigns a responsible individual to act as the QAR, and assigns a backup in case the QAR is absent, as appropriate, to ensure continued efforts in the laboratory Quality Program.

- 4.3.1.4 Visits or contacts customers to review customer requirements. Our goal is to survey one hundred percent of our customers on an annual basis. A Customer Survey form located in Appendix (F) is to be completed and filed with the QAR for each customer survey. Complaints or adverse comments toward calibration support will be investigated with corrective action and follow-up action taken, if applicable.
- 4.3.1.5 Maintains an authorization list or appointment letters, which identifies key laboratory personnel. A current copy of this list or appointment letters is maintained in the laboratory turnover folder.
- 4.3.2 The **Section Heads / Supervisors** (In some cases may also be the Calibration Chief) are responsible for all the overall administrative and technical operations of their respective areas of the laboratory. Major responsibilities include.
- 4.3.2.1 Ensures compliance to Quality Manual and approves all used methodologies.
- 4.3.2.2 Implements good laboratory practices and enforces these in day-to-day operations by providing instruction and training as needed and developing work plans and procedures.
- 4.3.2.3 Maintains training records and assigns only qualified personnel to perform calibrations.
- 4.3.2.4 Attests, by signature, to the validity of all laboratory tests, data entry and reports. This is accomplished by utilizing the "Approved By" field in Labmate or signing of Calibration Certificates.
- 4.3.2.5 Reviews all Calibration Problem Reports (CPR's) before submission to Naval Warfare Assessment Station, Measurement Science (MS-43), Corona, CA for engineering support. Hereafter referred as MS-43.
- 4.3.3 The **Quality Assurance Representative's (QAR)** major responsibilities include the following:
- 4.3.3.1 Schedules, conducts or assigns, and documents as appropriate, internal audits of the laboratory IAW Section 5 and Appendix (C) of this Quality Manual.
- 4.3.3.2 Coordinates external audits with the Calibration Chief and QPM.
- 4.3.3.3 Assigns responsible individuals to perform as Collateral Duty Inspectors (CDI's) as required to assist the QAR in performing inspections.
- 4.3.3.4 Performs Quality Verification Inspections (QVI's). QVI's are random and scheduled "In-Process" and "Final" inspections of the calibration process. The inspections are recorded on a Quality Verification Inspection (QVI) form IAW Appendix

- 4.3.3.5 (C) of this Quality Manual. The QAR reviews inspections performed by CDI's and takes appropriate actions IAW Appendix (C) of this Quality Manual. The QAR performs a minimum two percent Final Inspection on randomly selected completed TMDE utilizing the QVI form located in Appendix (D). The Final inspection consists of a partial or full re-calibration of completed TMDE. Ensures proper documentation of all quality issues.
- 4.3.3.6 Maintains, analyzes, and updates statistical data gathered from QVI's, internal audits, customer audits, and any other applicable data. This data is compiled and forwarded to the QPM monthly. This data is utilized to identify potential areas for training, monitoring, improvement and to detect trends.
- 4.3.3.7 Participates in available and relevant proficiency tests, inter-laboratory comparisons and maintains documented results for three complete calibration cycles.
- 4.3.3.8 Recommends to the Calibration Chief and QPM any improvements to the Quality Manual and Quality Program.
- 4.3.3.9 Has direct access to the Calibration Chief and to the QPM.
- 4.3.4 The **Collateral Duty Inspector's (CDI)** major responsibilities include the following:
- 4.3.4.1 In the absence of the QAR, perform duties normally assigned to the QAR.
- 4.3.4.2 Assist the QAR in conducting and documenting as appropriate, internal audits of the laboratory IAW Section 5 and Appendix (C) of this Quality Manual.
- 4.3.4.3 Performs QVI's as assigned by the QAR. The inspections are recorded on a QVI form. IAW Appendix (C) and Appendix (D) of this Quality Manual.
- 4.3.4.4 Recommends to the QAR any improvements to the Quality Manual and Quality Program.
- 4.3.4.5 Has direct access to the QAR.
- 4.3.5 The Calibration Technician's major responsibilities include the following:

Note: The Calibration Process located in Appendix (B) provides details for many of the following responsibilities.

4.3.5.1 Accurately performs calibrations using approved standards, documentation and good laboratory practices.

- 4.3.5.2 Researches the requirement for and applies all applicable modifications.
- 4.3.5.3 Observes required TMDE stabilization times. Ensures the laboratory environment is within limits at the beginning and end of calibration IAW applicable FR. Report any errors found in ICP's to section leader or supervisor.
- 4.3.5.4 Ensure all substituted standards meet specifications required by the approved calibration procedure.
- 4.3.5.5 Accurately enter all required calibration and repair data into Labmate and any other required software, hard copy form or document.
- 4.3.5.6 Follow documented calibration processes, adhere to all Calibration requirements within this Quality Manual and applicable Marine Corps documents.
- 4.3.5.7 In the absence of an ICP, follow the process identified in the Calibration Process located in Appendix (B). If unsure of a task, the technician has direct access to documented procedures in addition to the Section Heads for guidance.
- 4.3.6 The **Shipping and Receiving Personnel** (see Section 11 of this Quality Manual).

5 Quality Program, Audit and Review

The laboratory has established and maintains a Quality Program supporting the tests conducted by the laboratory. The Quality Program is described in this Quality Manual, appendices, and applicable sections of the references named therein. These documents are readily available to all laboratory personnel and serve as the basis for evaluating the measurement integrity of tests and associated reports. The laboratory periodically receives external audits carried out by the QPM to ensure that the laboratory's policies and procedures, as set forth in the Quality Manual, are being followed. The laboratory QAR also conducts and documents Internal Audits and Reviews to enhance continuous process improvement. The Calibration Chief conducts and documents the section of the internal audit verifying the Quality Program.

5.1 Quality Program

- 5.1.1 The basic elements of the Quality Program include the use of:
- 5.1.1.1 Supervision and quality reviews by Calibration Chief, Section Heads, CDI's and the QAR. See Section (4), Appendix (C), and laboratory turnover folder.
- 5.1.1.2 Qualified personnel for each measurement. See Section (6) and laboratory turnover folder, desktop procedures, and training records.

5.1.1.3 Environmentally controlled facilities and proper accounting of relevant environmental factors. See Section (7) and applicable FR document. Appropriately maintained and calibrated standards, TMDE, and associated apparatus. See Section (8). Approved methodology including approved instrument calibration procedures, good laboratory practices, and good measurement practices. See Section (10).

5.2 Quality System, Audit and Review

- 5.2.1 External audits (on-site assessments) are performed by the QPM at variable intervals to verify that the laboratory's operations, facilities, TMDE, standards, and personnel continue to comply with the requirements of Navy/Marine Corps METCAL policy and the ANSI/NCSL Z-540-1 (1994). External laboratory audits are conducted at a minimum of once every three years. External audit results are provided to PM TMDE and a copy forwarded to the Calibration Officer/Chief within thirty days from audit completion. All audit findings, and any corrective and follow-up actions that arise from them, are documented and promptly settled within the agreed time. Deficiencies are monitored through their acceptable completion and verified by the QPM.
- 5.2.2 Internal Audits and reviews (self-assessments) are conducted periodically IAW Appendix (C) to verify that operations continue to comply with the Quality Program. Audit results and if applicable, corrective and follow action are documented and forwarded to the QPM. Internal auditors are trained in auditing techniques and have technical insight concerning the laboratory's functions.
- 5.2.2.1 In addition to periodic audits, the laboratory ensures the quality of results by conducting in-process inspections and outgoing TMDE inspections IAW Appendix (C).
- 5.2.2.2 When internal audit/inspection findings cast doubt on the correctness or validity of the laboratory's calibration or test results, the Calibration Chief or Section Head investigates further and, if warranted, takes immediate action to notify in writing any customers whose items may have been affected.
- 5.2.3 Because quality is a continuous process improvement, unscheduled external or internal laboratory audits may be required when unexpected or unusual events occur which may cause a measurement outcome to be suspect. The following examples may initiate an unscheduled laboratory audit.
- 5.2.3.1 Identification of problem(s) arising as a result of any errors identified by the customer, or discrepant results from the analysis of laboratory test data. See Section (16).
- 5.2.3.2 Evidence from internal audits indicate non-compliance with laboratory Quality Program such as; quality verification inspections, statistical control data or charts that indicate a standard or measurement process may be suspect.

5.2.3.3 Evidence from external audits indicate non-conformance to standard criteria; or inter-laboratory comparisons or proficiency test results indicate a measurement outcome to be suspect. Uncertainty of Measurement: The measurement areas, ranges, and measurement uncertainties are documented in a Measurement Capabilities document and is kept in the Laboratory Turnover Folder.

6 Personnel

6.1 **Qualifications** All laboratory personnel are qualified in applicable areas, having completed formal training or documented OJT. Personnel are selected for laboratory assignments based on professional qualifications, including education and relevant experience. Staffing is sufficient to maintain the timely processing of the customers workload and comply with quality program requirements.

6.2 **Training**

Adequately trained personnel are a key factor in the performance of metrology related measurements. Metrologists have the necessary background in electronics and physical sciences to ensure a thorough comprehension of laboratory tests. Laboratory management and supervision communicate quality requirements and provide formal training and on-the-job training for laboratory personnel. Training is a part of normal laboratory operations and the training responsibility is identified in the laboratory turnover folder.

6.3 Resource Allocation

Utilizing staff resources, the Calibration Chief and Section Heads:

- 6.3.1 Implement and apply the procedures contained in the referenced documents listed in Section (2).
- 6.3.2 Provide and document ongoing training to ensure proficiency in calibration and testing.
- 6.3.3 Develop work plan schedules and require that personnel follow the procedures in day-to-day operations.
- 6.3.4 Assign tasks based on personnel training records, documented qualifications and QVI's.
- 6.3.5 Maintain training records and validate the metrologist's training and or background for assigned tasks.

7 Laboratory Facilities and Environmental Controls

7.1 Facilities and Conditions

- 7.1.1 The laboratory facilities are maintained IAW the applicable FR document, to support measurement integrity, and good laboratory practices. See the laboratory turnover folder for a diagram of the laboratory's facilities. The diagram identifies each Section of the laboratory, i.e., General Purpose Electronics, AC-DC, Microwave, Physical/Dimensional, Electro-Optics etc. Also, includes approximate size of each area and the total size of the facility. The laboratory facilities, calibration and test areas, energy sources, lighting, heating, ventilation, and air conditioning system facilitate proper performance of calibrations in process. The Calibration Chief and Section Heads ensure that dust, electromagnetic interference, humidity, line voltage, temperature, sound and vibration levels are maintained at acceptable levels IAW the applicable FR document for specific measurements, and associated uncertainties. When laboratory environmental testing is contracted outside the laboratory, i.e. Base Occupational Health, the results are maintained on file for three years or until re-testing.
- 7.1.2 When environmental conditions for the particular measurement deviates from those listed in the applicable FR document, the laboratory stops calibrations in that measurement area. Calibrations may continue in specific instances when an evaluation is conducted by the Calibration Chief. A statement is added by the technician in the "Notes" field in Labmate to the evaluation and approval for calibration.
- 7.1.2.1 Verify that air conditioning, lighting, heating, and ventilation are controlled and monitored to the level needed for each type of test.
- 7.1.2.2 Maintain good housekeeping practices to promote a clean, uncluttered laboratory.
- 7.1.2.3 Have sufficient space to minimize the risk of injury to staff or damage to laboratory standards and other TMDE due to activities around test setup.
- 7.1.2.4 Maintain a convenient and efficient work environment with effective separation of incompatible measurement areas, due to different temperature requirements or safety.
- 7.1.2.5 Exceptions to the applicable FR document may be granted and published by MS-43, communicated to all laboratory personnel, and maintained in the laboratory's turnover folder.

7.2 Environmental Records

7.2.1 The laboratory monitors and records the temperature and humidity of each measurement area within the laboratory by date, time and location. In some instances, compatible measurement areas in close proximity are monitored by the placement of one thermo-humidigraph.

7.2.2 The laboratory maintains a historical record of environmental conditions during all testing periods by annotating applicable dates, location, and signing the expended charts to indicate they were reviewed will accomplish this. The completed charts are then retained for a minimum of three years. The laboratory documents deviations and corrective actions when environmental conditions are not within conditions specified by the applicable FR document. This documentation is accomplished by the Calibration Chief, Section Head or QAR signing the environmental chart and briefly annotating any corrective action taken next to any recorded deviation. This documents that the deviation was noticed and corrective action taken when possible.

8 Laboratory Equipment, Standards, and Reference Materials

8.1 **Laboratory TMDE**

- 8.1.1 Laboratory TMDE, reference material and ancillary equipment are suitable for the correct performance of calibrations and tests and used or operated only when in a safe and reliable condition and by personnel who have been trained and are qualified.
- 8.1.2 Newly installed TMDE and ancillary equipment is calibrated/tested to verify satisfactory performance prior to being placed into service. Documentation of this verification is either, received with the TMDE and maintained in laboratory files, or is maintained in Labmate. TMDE Software is verified and approved by MS-43 prior to use.
- 8.1.3 Laboratory TMDE is maintained to ensure proper performance, protected from causes of deterioration, and properly operated.
- 8.1.4 Operation manuals and instructions for proper maintenance of TMDE are available to all personnel and located in the laboratory.
- 8.1.5 Maintenance and calibration records for laboratory TMDE are documented in Labmate. Documented data includes the following:
- 8.1.6 Item name, manufacturer, model, serial and other identification numbers.
- 8.1.7 Date and condition of receipt, date placed in service, and current location.
- 8.1.7.1 History of calibration, maintenance, malfunctions, modification, and repair.
- 8.1.7.2 Measured value observed for each parameter found to be out of tolerance.
- 8.1.7.3 Calibration procedure, status and re-certification date.

8.2 Standards

- 8.3 (also see Section 9, "Measurement Traceability and Calibration")
- 8.3.1 The laboratory maintains calibration, verification, maintenance documentation, and records of all laboratory standards. To maintain integrity of the standards, all maintenance operations and subsequent calibrations are performed according to documented procedures. Laboratory standards are:
- 8.3.2 Selected for use according to the level of precision, accuracy, and uncertainty required.
- 8.3.3 Limited in access and used by trained and authorized laboratory personnel only.
- 8.3.4 Not utilized as repair TMDE.
- 8.3.5 Handled and safely stored according to good laboratory practices.
- 8.3.6 Labeled, marked, or otherwise identified to indicate the calibration status.

8.4 Suspect / Out-of-tolerance Equipment

- 8.4.1 Any item of TMDE which has been subjected to overloading or mishandling or which gives suspect results or has been shown by verification or otherwise to be defective is taken out of service. Clearly identify the item as suspect with a red reject tag, and whenever possible, store in a specified place until repaired and demonstrated by calibration, verification, or test that the item performs satisfactorily.
- 8.4.2 If standards are found to be out-of-tolerance, the QAR and Section Head are notified immediately. If applicable, a reverse traceability report is generated with Labmate and evaluated. The Calibration Chief, Section Head and QAR determine depth of recall if deemed necessary. Customers are notified immediately in writing or E-mail and provided a list of TMDE that is to be considered suspect to be returned for verification. Records of corrective actions are maintained by the QAR.

Note: One method used to determine the depth of recall is by half splitting the maximum timeframe of the suspect calibrations, recalling a sample size of TMDE, and analyzing the calibrated TMDE. The half splitting is continued until the timeframe can be determined and then a recall is performed.

9 Measurement Traceability and Calibration

9.1 Traceability

The laboratory achieves traceability through an unbroken chain of comparisons to National or International Standards through the Marine Corps Measurement Transfer Standards Program, NPSL, and other certified primary standards laboratories.

- 9.1.1 Primary standards are calibrated and traceable to the Navy Primary Standards Laboratory (NPSL), National Institute of Standards and Technology (NIST), U.S Naval Observatory, or other Marine Corps approved sources. Reports of Calibration are maintained in the laboratory files, as appropriate.
- 9.1.2 Working standards are calibrated by comparison to primary standards using documented instrument calibration procedures. These standards are also traceable through an unbroken chain of comparisons to NSPL, NIST or other approved sources.

9.2 Calibration Procedures

The laboratory utilizes NAVAIR 17-20 series Instrument Calibration Procedures (ICPs) and other approved procedures in conjunction with the traceable standards. Refer to Section (10) and Appendix (B). Each procedure lists the required laboratory standards to calibrate the unit under test and provides step-by-step instructions in the calibration process.

9.3 Calibration of Standards

Laboratory standards are monitored for stability and are calibrated or verified before use.

9.4 Recall of Standards Due Calibration

A recall list of all laboratory standards and TMDE due for calibration is generated on a monthly basis using Labmate. Prior to the calibration due date all laboratory TMDE due for calibration is segregated to a clearly marked area to prevent accidental use, or red tagged and annotated "Do Not Use Until Calibrated".

9.5 Calibration Intervals

MS-43 is tasked by PM TMDE to perform engineering analysis on laboratory standards and TMDE; and establish, maintain and distribute calibration intervals. To ensure the most accurate data is analyzed for interval analysis, it is our policy to only make adjustments to TMDE that is found out-of-tolerance. See section 13.3 for customer notification.

10 Calibration Test Methods and Procedures

10.1 Calibration Methods

Primary test methods for calibration are contained in approved NAVAIR 17-20 series ICP's, Department of Defense (DoD) ICP's, LCP's (Local Calibration Procedures) and software. These procedures provide important information pertaining to the identification of the item under test, required laboratory standards, proper set up/connections, step-by-step instructions in the calibration process, and include the required parameters for each test.

10.2 Laboratory Procedures

The laboratory maintains administrative and measurement-related operating procedures in the laboratory files. These procedures are available to laboratory personnel and are followed to ensure the integrity of administrative duties, calibrations, and test results. Also, equipment manuals, operating instructions, reference data, specifications, and tolerance tables relevant to laboratory calibrations and tests are maintained in an up-to-date file in the laboratory, and are readily available.

10.3 TMDE Without ICP's

When approved calibration procedures are unavailable, the laboratory may use procedures published in relevant scientific texts or journals from reputable technical organizations ensuring a minimum of a 4 to 1 Test Accuracy Ratio (TAR) is maintained wherever possible. At a minimum, a checklist is developed and maintained on file to document what parameters were verified. This allows the replication of the calibration. When documented or published procedures are unavailable, the laboratory contacts MS-43 for engineering support. See Appendix (B). The completed calibration work order receipt or Calibration Certificate if provided, states the procedure used. Departure from documented policies and procedures are entered in Labmate and annotated on a "special calibration tag, if applicable, and affixed to the TMDE. The Calibration Chief or Section Head approves records regarding departures from documented policies, procedures or from standard specifications by the "approval" block in Labmate or signing in the "reviewed by" field on the Calibration Certificate.

10.4 Administrative Procedures

Administrative procedures are identified in the laboratory "turnover" folder or "desktop" procedures. They are developed by the laboratory and maintained by the Calibration Chief or designated representative/s. The administrative procedures ensure that the overall operations of the laboratory promote the quality and integrity of calibration, test results, and test items.

10.5 Computer Software Procedures

Software that affects the quality and integrity of calibration, test results and test items is verified prior to use. MS-43 is the software verification and approval authority for Marine Corps calibration laboratories (See Appendix B, paragraph 4). Where computers, instrument controllers, and microprocessor based resources are involved in automated test procedures, data recording, data retrieval, data processing, data calculation, data analysis, or reporting, the laboratory ensures that:

- 10.5.1 The requirements of this manual are maintained.
- 10.5.2 Computer software has been documented and verified prior to use.
- 10.5.3 Procedures are established to:
- 10.5.3.1 Protect the integrity of stored data.

- 10.5.3.2 Provide limited access to maintain security of the programs in use.
- 10.5.3.3 Back-up programs and records to prevent loss.
- 10.5.3.4 Revise software if authorized updates occur.

11 Receipt, Handling and Storage of Items Requiring Testing or Calibration

11.1 Receipt of Equipment

- 11.1.1 Items received for test or calibration are entered into Labmate by an assigned BCN (Bar Code Number). If no BCN has been assigned, the person receiving the TMDE into the laboratory assigns the BCN. The BCN is the unique identifier used to track the item through its lifecycle. A work order is generated which includes: the item or items received for test, BCN, model number and name of customer submitting the test items, and date of receipt. Work order tags are attached to, and kept with the test item during the maintenance process.
- 11.1.2 Incoming test items are evaluated by appropriate laboratory staff to ensure that the appropriate standards, TMDE, staff, facilities, and procedures necessary to perform testing are available. Procedures for the receipt and review of all incoming work are listed below and may be amplified in laboratory desktop procedures.

11.2 Handling

TMDE is tagged, segregated and stored in clearly marked areas in a safe manner to protect them from loss, deterioration, damage, vibration, and broken chain of custody and when relevant, in environmentally controlled conditions.

11.3 Pre-induction Inspection

- 11.3.1 As assigned by the Calibration Chief, the designated inspector (normally the shipping and receiving personnel) will:
- 11.3.1.1 Visually inspect all incoming TMDE for cleanliness and damage, and ensure receipt of proper shipping documents, when applicable.
- 11.3.1.2 Ensure that all data entered into Labmate matches actual TMDE identification such as; model/part number, serial number, manufacturer, condition received, and customer information.
- 11.3.1.3 Ensure that all accessories and publications received, and services requested including special instructions are annotated in Labrate.

11.3.1.4 Notify the Calibration Chief, QAR, and Customer, as appropriate, of discrepancies found.

11.4 Shipping Procedures for Calibrated Equipment

- 11.4.1 All processed TMDE leaving the laboratory shall be visually inspected. This preshipping inspection provides a final review of outgoing customer's TMDE. Upon completion of calibration or testing, the completed items are returned to the customer in a manner that will ensure that the integrity of the calibration is preserved at all times.
- 11.4.2 As assigned by the Calibration Chief, the designated inspector (normally the Shipping and Receiving personnel) will:
- 11.4.2.1 Visually ensure that outgoing TMDE is in good physical condition and not damaged. Exceptions are; any TMDE with damages documented in Labmate that were present upon receipt and the customer stated to not repair the noted damage, or the damage is cosmetic in nature.
- 11.4.2.2 Ensure that appropriate paperwork is attached to the TMDE and all documentation is complete.
- 11.4.2.3 Ensure all calibration labels and tags are applied as identified in Labmate and IAW TI 4733-15/1_ and old labels have been removed (e.g. Current calibration due date, Special Calibration parameters annotated on tag and correct number of Calibration Void seals applied).
- 11.4.2.4 Verify ancillary items (cables, test fixtures, publications, etc.) received with the TMDE are returned and annotated on the appropriate paperwork.
- 11.4.2.5 If applicable, laboratory personnel advise appropriate personnel of any special packing/shipping instructions to include using packing material to protect all sides of equipment paying particular attention to display screens, controls, and connectors. All TMDE received in special shipping containers will be returned in the same container.

11.5 Shipping of TMDE for Repair and / or Calibration

- 11.5.1 TMDE is handled and packed to prevent any damage or excessive vibration. This includes using 2 to 4 inches of packing material to protect all sides of equipment paying particular attention to display screens, controls, and connectors.
- 11.5.2 Documentation accompanies all TMDE and clearly states the services requested.
- 11.5.3 Any TMDE requiring repair is clearly marked by attaching a red "Reject" tag with information pertinent to the required repair.

11.5.4 All TMDE received in special shipping containers will be returned in the same container.

12 Records

12.1 Security of Records

The laboratory maintains and ensures the safety and security of calibration records. The Labmate database is backed-up daily. All personnel using Labmate are assigned security levels that permit necessary access while providing security. Calibration data entered into Labmate contains sufficient detail to, if necessary, permit the repetition of measurements.

12.2 Category of Records

Records maintained by the laboratory are in three categories: Administrative, measurement-related, and process measurement quality assurance. These laboratory records are maintained in a current state and communicated to all laboratory personnel, as required.

12.3 Content of laboratory documents

Documents of administration functions, operational procedures, and quality verification data include:

- 12.3.1 Instructions, directives, procedures, guidelines and other documents listed in Section 2 of this manual.
- 12.3.2 The record of inspection for material and parts that are used in TMDE is the entry of the items use into Labmate by the user.
- 12.3.3 The following is a list of laboratory quality-related records and are retained for three years:
- 12.3.3.1 QVI forms and any subsequent actions on nonconformances.
- 12.3.3.2 Internal audit results.
- 12.3.3.3 Customer survey / Complaint forms.
- 12.3.3.4 Labmate records that contain repair, modification and calibration data specific to each item of TMDE.

12.4 Access to Computer Records

Records contained in computer files, are accessible to authorized personnel only and are backed-up for protection against loss.

13 Certificates and Reports of Calibration

13.1 Certificates of Calibration

Any Certificates of Calibration or Reports of Calibration developed by Marine Corps Calibration Laboratories are in compliance with Appendix B of TI-4733-35/23_. MARCORSYSCOM, PM TMDE is the approving authority of any exceptions.

13.2 Amendments to Certificates of Calibration

Amendments to certificates and reports of calibration after issue are made in the form of a further document or data transfer that includes the statement "Supplement to the Report of Calibration." Records of these documents are maintained by the laboratory staff and located in the laboratory files (see Section 12, "Records," Certificates and Reports of Calibration/Supplements to Calibration and Test Reports).

13.3 Notification of Customers

The laboratory notifies its customers in writing of any events, which cast doubt on the validity of the results given in any calibration report or amendment to a report.

13.4 <u>Customers TMDE found Out-of-Tolerance</u>

Customers whose TMDE was received in an out-of-tolerance condition are promptly notified in writing by the inclusion of the measurement data on the ERO or Calibration Certificate. This measurement data is entered and maintained in Labmate.

13.5 Retention of Records

Reports or certificates of calibration generated by the Measurement Transfer Standards (MTS) program or outside calibration service providers are kept on file for a minimum of three years.

14 Subcontracting of Calibration

14.1 Compliant Subcontractors

The laboratory only uses subcontractors that meet the requirements of ANSI/NCSL Z540-1 in accordance with MCO 4733.1_, or sub contractors that are in process of compliance and that have been evaluated by the QPM and determined to meet necessary quality criteria to provide limited sub contractor support. The QPM oversees and conducts all investigations utilizing Appendix (H) and maintains results of investigations. Approved service providers are listed on the PM TMDE web site at http://iis.marcorsyscom.usmc.mil/PM TMDE.

14.2 Labeling

Labeling, including calibration intervals by outside service providers will be accepted IAW MCO 4733.1 .

15 Outside Support Services and Supplies

15.1 Quality Supplies

Where specifications of outside services and supplies are relevant to the measurement integrity of tests, the laboratory uses services and supplies of adequate quality.

15.2 Inspection of Supplies Before Use

The laboratory maintains procedures for the purchase, storage, and evaluation of supplies and services. The laboratory uses these items only after they have been inspected or otherwise verified for adequate quality. The complexity of this inspection / verification is based on practicality and capability. At a minimum, the user performs a visual inspection before use of materials and parts. The entry of materials and parts into Labmate serves as the records of inspection.

16 Complaints and Corrective Action

16.1 **Documentation of Customer Complaints**

In the event of adverse findings during audits, or any other circumstance, which raises doubt concerning the laboratory's competence or compliance with required procedures, the laboratory ensures that those areas of activity and responsibility involved are promptly investigated. A resolution of the adverse situation is promptly pursued and, where necessary, re-testing is conducted. The investigation, results, and resolution are documented by the QAR and maintained on file for three years.

16.2 Resolution of Customer Complaints

In the event of customer complaints, the Calibration Chief is responsible for prompt resolution. The QAR is informed of all customer complaints and normally performs the investigation and seeks to identify the specific root cause. The QAR documents information on the Customer Survey / Complaint form (Appendix F) identifying the complaint, corrective action taken and follow-up actions to ensure that corrective action is appropriate. The Customer Complaint form along with any documents pertaining to the complaint or resolution are filed and maintained by the QAR.

17 Site Security

17.1 Security Procedures

The Calibration Chief is responsible for security directly related to the laboratory and designates specific duties of on-site security to the laboratory staff. Security of the laboratory premises includes the following:

- 17.1.1 Locking laboratory doors as applicable to control access.
- 17.1.2 Securing all doors and perimeter at the close of the day.
- 17.1.3 Securing all areas where laboratory standards and TMDE are stored or maintained.

17.1.4 In some cases, management at higher level establishes policy and responsibility for security. In these cases, the document defining these special instances, is located in the turnover folder.

17.2 Access

- 17.2.1 Access to and use of all measurement areas is controlled and defined by the Calibration Chief. The laboratory maintains the current access list by name and phone number. Names and phone numbers of designated laboratory security representatives are posted on the access doors in the event of an emergency. The Calibration Chief assigns laboratory personnel to perform collateral security duty.
- 17.2.2 In the event that cleaning is performed by non-laboratory personnel, they are only allowed supervised access to the laboratory.
- 17.2.3 Visitors are escorted to the degree necessary to maintain laboratory and measurement integrity.

18 Safety

18.1 **Safety Procedures**

Safe working conditions are prerequisite to good laboratory practices. Laboratory personnel are instructed in safe working practices and are encouraged to look for hazardous conditions as well as recommend and implement accident prevention.

18.2 Compliance of Safety Regulations

The Calibration Chief and Section Heads ensure safe working conditions, and that all personnel comply with safety regulations.

18.3 Personnel Responsibilty

It is the responsibility of all personnel to be familiar with and comply with all safety guidelines and requirements that are posted or identified in laboratory documentation.

APPENDIX A

Definitions

Calibration - A set of operations which establish, under specified conditions, the relationship between values indicated by a measuring instrument or measuring system, or values represented by material measure, and the corresponding known values of a measurand. Also: comparison of a measurement standard or instrument with another standard or instrument to detect, correlate, report, or eliminate by adjustment any inaccuracy of the compared.

Calibration Method - Defined technical procedure for performing a calibration or verification.

Corrective Action - An action taken to eliminate the causes of an existing deficiency or other undesirable situation in order to prevent recurrence.

Deficiency - The non-fulfillment of appropriate conditions or criteria required to perform calibrations.

External Audit - Appraisal of a calibration or testing laboratory by an outside body, using specified criteria and checklists to evaluate compliance of stated specifications.

Good Housekeeping – Cleanliness of the laboratory and organization and storage of reference materials and TMDE.

Good Laboratory Practices (GLP) - An acceptable way to perform some basic operation or activity in a laboratory that is known or believed to influence the quality of its outputs. GLPs ordinarily are essentially independent of the measurement techniques used.

Good Measurement Practices (GMP) - An acceptable way to perform some operation associated with a specific measurement technique that is known or believed to influence the quality of the measurement.

In-process verification - A form of QVI (quality verification inspection) – an operation to determine if certain procedures that have been determined to affect the quality of a product or service are being followed.

Inter-laboratory Comparisons - Organization, performance, and evaluation of calibrations or tests on the same or similar items or materials by two or more laboratories IAW predetermined conditions.

Quality Manual

Internal Audit - The process of self appraisal of a calibration or testing laboratory using specified criteria and checklists to evaluate compliance of stated specifications; may be used as a quality management review as well.

Measurand - A quality subjected to measurement (Note: As appropriate, this may be the "measured quantity" or the "quantity to be measured")

Measurement - The set of operations having the object of determining the value of a measurand.

Measurement Assurance - A process to ensure adequate measurement results that may include, but is not limited to: 1) use of good experimental design principles so that the entire measurement process, its components, and relevant influence factors can be well characterized, monitored, and controlled; 2) complete experimental characterization of the measurement process uncertainty including statistical variations, contributions from all known or suspected influence factors, imported uncertainties, and the propagation of uncertainties throughout the measurement process; and 3) continuously monitoring the performance and state of statistical control of the measurement process with proven statistical process control techniques including the measurement of well-characterized check standards along with the normal workload and the use of appropriate control charts.

Measurement Standard - A material measure, measuring instrument, reference material or system intended to define, realize, conserve or reproduce a unit or one or more known values of a quantity to serve as a reference.

Measuring Instrument - A device intended to make a measurement, alone or in conjunction with supplementary equipment.

Nonconformance - Non-fulfillment of a specified requirement.

On-Site Assessment - A formal examination or official inspection of a calibration or testing laboratory to evaluate its compliance with specific laboratory criteria.

Preventive Action - An action taken to eliminate the causes of a potential deficiency or other undesirable situation in order to prevent occurrence.

Process - Set of inter-related resources and activities which transform inputs into outputs.

Procedure - Specific way to perform an activity.

Product - Result of activities or processes

Proficiency Testing - The determination of laboratory performance by means of comparing and evaluating calibrations or tests on the same or similar items or materials by two or more laboratories IAW predetermined conditions.

Quality - The totality of features and characteristics of a product or service that bear on its ability to satisfy stated or implied needs.

Quality Audit - A systematic examination or evaluation of the extent to which an entity is capable of fulfilling specified requirements; a systematic and independent examination to determine whether quality activities and related results comply with planned arrangements, whether these arrangements are implemented effectively and are suitable to achieve objectives, and whether the quality control system is operating within acceptable limits.

Quality Manual - A document stating the quality policy, quality system and quality practices of an organization. (Note: The quality manual may call up other documentation relating to the laboratory's quality arrangements).

Quality System - The organizational structure, responsibilities, procedures, processes and resources for implementing quality management.

Quality Verification Inspection - In-Process or Final Inspection to verify compliance of documented processes, verify quality of calibration service, and to identify areas for improvements.

Standing Operating Procedure (SOP) - A procedure adopted for repetitive use when performing a specific measurement or sampling operation. It may be a standard method or one developed by the user.

Standard, Primary - A standard that is designated or widely acknowledged as having the highest metrological qualities in a specified field; a substance, object, or scale, the value of which has been established by a reliable source, and which can be accepted (within specified limits) without question when used to establish the value of the same or related property of another similar object or scale. Note that the primary standard for one user may be a secondary standard for another.

Standard, Reference - A standard, generally of the highest metrological quality available at a given location, from which measurements made at that location are derived.

Standard, Secondary - A standard whose value is assigned by comparison with a primary standard of the same quantity.

Standard, Working - A standard, usually calibrated against a reference standard, which is used routinely to calibrate or check material measures or measuring instruments.

Tolerance Testing - A measurement operation performed to determine whether the actual value and uncertainty of a standard, artifact, or instrument is within a permitted tolerance of its nominal value.

Traceability - The property of a result of a measurement whereby it can be related to appropriate standards, generally national or international standards, through an unbroken chain of comparisons. (Note: The Navy Primary Standards Laboratory is a recognized and approved activity; traceable to national standards.

Uncertainty of Measurement - Parameter, associated with the result of a measurement, that characterizes the dispersion of the values that could reasonably be attributed to the measurand.

Uncertainty, Type A (evaluation of) - Method of evaluation of uncertainty by the statistical analysis of the measurement process.

Uncertainty, Type B (evaluation of) - Method of evaluation of uncertainty by means other than the statistical analysis of the measurement process.

Verification - Confirmation by examination and provision of evidence that specified requirements have been met.

Note: The above definitions are extracts from ANSI/NCSL Z-540-1 (1994) and other recognized standards.

Acronyms

ANSI - American National Standards Institute

APM CTMS - Assistant Program Manager, Calibration TMDE Management Systems

CDI - Collateral Duty Inspector

CPR - Calibration Problem Report.

DoD MIDAS - Department of Defense Metrology Information and Documentation Automation System

ERO - Equipment Repair Order

ESD - Electrostatic Discharge

ICP - Instrument Calibration Procedure

MARCORSYSCOM - Marine Corps Systems Command

MCO - Marine Corps Order

METCAL - Metrology Calibration

MS-43 - Naval Warfare Assessment Station, Measurement Science, MS-43, Corona, CA

NCO - Non Commissioned Officer

NCSL - National Conference of Standards Laboratories

NIST - National Institute of Standards and Technology

NPSL - Navy Primary Standards Laboratory

OOT- Out of tolerance

PM TMDE - Program Manager, Test Measurement and Diagnostic Equipment

QAR - Quality Assurance Representative

QPM - Quality Program Manager

QVI - Quality Verification Inspection

SNCOIC - Staff Non-Commissioned Officer In Charge

TAMS - Test and Measurement Systems

TMDE - Test Measurement and Diagnostic Equipment

APPENDIX B

Calibration Process

- 1. Select assigned test instrument (TI) from Labmate, according to priority of work or supervisory direction. Obtain TI from awaiting work shelf. Ensure serial number and model number coincide with Labmate data, if not, notify Section Head or receiving personnel. Ensure accessories remain with TI. Make appropriate "Log In" entries in Labmate to place the TI in work.
- 2. If an "In-Process" inspection is required, contact appropriate Quality Assurance personnel prior to starting calibration.
- 3. Perform visual inspection of TI. Perform any requested or required repairs or modifications. Perform any maintenance that might be required such as filters, batteries, cleaning, etc. If any "Calibration Void Seals" were broken when the TI was received, make an entry into Labmate.
- 4. Determine the current calibration procedure, revision and interval using DoD Midas or other appropriate source. The order of precedence is NAVAIR ICP, other DoD ICP or approved LCP. In the event an approved calibration procedure is not available, FMF Calibration Laboratories follow sub paragraph a, and the Depot Calibration Laboratories follow sub paragraph b for the development of a hardcopy local calibration procedure (LCP), sub paragraph c for software LCP.
 - a. <u>FMF Calibration Laboratories</u> do not normally develop LCP's. If an FMF Calibration Laboratory receives an item to calibrate that is not supported by an approved ICP, the FMF Calibration Laboratory requests guidance by providing the following information to PM TMDE/CTMS via E-mail or fax.
 - 1) Command submitting TMDE for calibration.
 - 2) Manufacturer
 - 3) Model Number
 - 4) Nomenclature
 - 5) Calibration Laboratory's recommendation on support of TMDE.

PM TMDE will respond with concurrence or non-concurrence with the laboratory's recommendation. If calibration is performed using a "like item" ICP and not deviated from, the ICP number is entered into Labmate. If the calibration is performed according to the manufacturer's procedure or a "like item" ICP with deviations, sufficient data is entered into Labmate to permit the replication of the calibration.

- b. <u>Depot Calibration Facilities</u> develop, control and revise LCP's using criteria found in ISO 9002, Maintenance Center Procedure P5.1, Document and Data Control. NAVAIR 17-35TR-4 will be used as a guide. See Figure 1 for Cover Page Format. The Section Head will be notified prior to the development of the LCP and has the responsibility to technically verify the LCP after development. Configuration Data Management Office is contacted for an LCP number. After development and technical verification, the LCP is forwarded to the QAS for acceptance. The LCP is then forwarded to the Calibration Manager for approval signature. After approval, the Calibration Manager forwards the signed copy and an electronic copy to the Configuration Data Management Office for reproduction and distribution to both depots, and MS-43 IAW P5.1. At this time, the LCP may be utilized for calibration by the depot that developed the LCP. Software utilized for calibration of FMF assets travels through the same process as LCP's.
- 5. Verify that the standards bear evidence of current calibration and that there are no "Special Calibration" limitations that might render the selected standard unsuitable for the calibration process.

Note: If a calibration standard is discovered to be out-of-tolerance, the Section Head and QAR shall be notified.

- 6. If standards are to be substituted, ensure that standards selected meet the "Minimum Use Specifications" listed in the calibration procedure. The Section Head or QAR must approve the substitution/s. (Note: The Navy Calibration Equipment (NCE) List found in DoD MIDAS provides a suitable substitutes list)
- 7. Perform the calibration process, ensuring each step is followed and that all specifications are met.
 - a. If an out-of-tolerance condition is encountered, document "as found" value and initiate corrective action.
 - b. Ensure all ESD precautions are observed.
 - c. If alignment or repairs are performed, re-verify previously calibrated steps to ensure that alignment/repair has not caused unexpected results.
- 8. If the test instrument is new and requires repair, (even if the test instrument has been in storage for an extended period) notify QAR. A PQDR should be written and submitted for possible warranty repair/replacement.

Quality Manual

- 9. In case of suspected ICP errors, check the web site at http://metrology.corona.navy.mil/secure/metserve.cfm to see if a CPR has already been submitted. If no CPR has been generated, and it is determined there is an error in the procedure, have the Section Head or QAR verify the problem and submit a CPR. Maintain a copy of the CPR as appropriate. (Note: TMDE calibrated after the submission of a CPR may be suspect if the CPR or recommendation is found invalid. TMDE determined to be suspect is recalled by the calibration laboratory.)
- 10. After the calibration process is complete, ensure appropriate (including out-of-tolerance) information is entered into Labmate. Apply all required labels IAW TI-4733-15/1_. If "CALIBRATED" or "SPECIAL CALIBRATION" label is not applied directly to the test instrument, record s/n on label and tag if applicable.

LOCAL CALIBRATION

PROCEDURE

LCP-AAM-xxx

NOMENCLATURE
MANUFACTURER
MODEL NO.

Electronics Business Center Maintenance Center Marine Corps Logistics Base Albany, Georgia 31704-1128

Prepared by:	Name	Date Prepared/Modified:	MO/DAY/YEAR
Verified by:			
	Section Head/Date		
Accepted by:			
	Quality Assurance/Date		
Approved by:			
•	Head, Electronics Business Ce	nter/Date	
	Figure 1. Sample LCP Cover	Page Format (Depot Use))

APPENDIX C

Laboratory Internal Quality Program

The Quality Assurance Representative (QAR), is the laboratory's focal point in the Quality Program. Collateral Duty Inspectors (CDI's) are experienced personnel who assist the QAR. The QAR reviews all Quality Verification Inspections (QVI's) performed by CDI's, and performs/coordinates and documents scheduled internal audits of the laboratory to the Quality Standard TI-4733-35/23_. In the absence of the QAR, a CDI may perform duties normally assigned to the QAR. The QAR performs "follow-up" action on non-conformances identified on the QVI's and internal audits to ensure effectiveness of corrective actions. The QAR maintains quality records for three years, and reports all applicable quality data, as summaries or reports to the Calibration Officer/Chief and the Quality Program Manager (QPM).

(Note: The QPM continually interrelates with each calibration laboratory to provide assistance, and collect quality data and information. This reduces duplicate effort between the laboratories, provides a greater scope of analysis to base decisions and optimizes the efficiency of the laboratory quality personnel.

- 1. The Section Heads nominate experienced technicians that are familiar with the laboratory's processes and the laboratory operation for QAR and CDI duties.
- 2. Training for the QAR's and CDI's is conducted and documented by the QPM.
- 3. Ten percent of TMDE processed through the laboratory receives a randomly selected inprocess QVI. The CDI thoroughly verifies a minimum of one completed calibration step and enters inspection data on a QVI form located in Appendix (D). The completed QVI is routed to the QAR for review, appropriate action and data collection. The selection process is defined in the turnover folder and all laboratory personnel understand the process. If an out-of-tolerance condition is discovered during a QVI, the CDI takes appropriate action to ensure all parameters are in-tolerance. The QAR may perform the in process inspection.
- 4. In case of non-conformances, the CDI recommends corrective action or provides instruction, and documents in the remarks section of the QVI.
- 5. The QAR reviews, signs and maintains the QVI forms. If during the QAR review, non-conformances are noted, the QAR performs follow-up action verifying that corrective action was effective and documents the follow-up action on the QVI form.
- 6. The QAR randomly selects a <u>minimum</u> of two percent of completed test instruments from the outgoing shelf for a Final Inspection. The total number of items calibrated is continuously monitored and inspections adjusted accordingly.
- 7. The QAR (after notifying the Section Headl) has the item partially or completely calibrated and documents the results on a QVI form. The extent of the inspection is dependent on the inspected item. Items that take over an hour to calibrate, may receive a partial re-calibration.

- 8. The QAR investigates non-conformances to identify the root cause i.e. equipment, methods, or technician error. The technician documents any corrective action/s on the QVI form if non conformances were identified. The QAR conducts a follow-up audit to verify that corrective action was effective for all noted non-conformances and documents the follow-up action on the QVI form. The QVI form is retained as a quality document and to extract data from to forward to the Quality Program Manager (QPM). This data is statistically analyzed to identify trends, and areas to focus on for continuous improvement. If any measurements are found to be out of tolerance due to technician error, the QAR will complete a one hundred percent verification of three of the technician's completed items still on the outgoing shelf or the next three items calibrated. If more non-conformances are found, the QAR and Section Head investigate to find the root cause of the non-conformances and initiate corrective action. The QAR takes follow-up action to verify effectiveness.
- 9. Internal audits are carried out, at a minimum, during the anniversary month of the certification audit. The purpose of this audit is to verify that the laboratory is maintaining compliance to TI-4733-35/23_. The QPM provides the auditing criteria to the QAR during the month prior to the anniversary month. The QAR conducts the internal audit, documents results, and discusses results with the Calibration Chief. If areas of nonconformance are discovered, the Calibration Chief is responsible to take corrective action as soon as possible. The QAR verifies the corrective action is effective and documents the follow-up action. The QAR forwards a copy of all internal audit documents to the QPM at the end of the anniversary month. If follow up actions are not complete, those documents are forwarded when completed. The QPM may elect to conduct the annual internal audit or schedule a trained Marine Corps Lead Auditor to conduct the annual internal audit.

Note: In addition to the structured Quality Assurance Program, Section Heads attest by signature, to the validity of all laboratory tests and reports. This is accomplished by utilizing the "Approved By" field in Labmate or signing of Calibration Certificates.

Appendix D

Quality Verification Inspection (QVI) Form

TI Nomenclature:			Mod	el:		
ICP# Labmate ID#	Date:					
First Cal Tech:	S	ecor	nd Cal	Tech:		
Inspection Type: In Process Step/s #:						
Final: Full: Partial:				1/5.		
Tuna Tuna Tunan	-		0000.0.			
	Υ	N	N/A	REMARKS		
Were abnormalities including damage to TMDE						
documented in Labmate during the receiving process?	<u> </u>					
2. If repairs were made, was the TMDE returned to the						
original configuration? (i.e. soldering, hardware)						
3. Was repair data entered into Labmate?	<u> </u>					
4. Did the technician follow the latest revision of the						
proper calibration procedure?						
5. Is there an open CPR against the ICP for longer						
than 30 days? If so, for how long has it been open?						
6. Is the ICP free of unauthorized notes?						
7. Has the technician received training in this				Type:		
measurement area on this type of equipment or in				Date:		
OJT? For OJT, enter type and date of training.						
8. Were the specified standards or suitable substitutes						
used?						
9. Did the environmental conditions meet those		ĺ				
required for the measurement area and uncertainty						
and documented in Labmate?						
10. Are all measurements within tolerance?						
11. Is workbench ESD safe and free of clutter?				·		
End of In-Process Inspection ************************************	**	**	***	************		
12. If TMDE was received OOT, is the measurement	}					
data entered on ERO or Cal Cert to notify customer?						
13 Are Calibration Labels, Tags and Cal Void Seals	i					
applied IAW TI-4733-15/1?						
14. Is the calibration interval correct?		<u> </u>				
15. Was all calibration data i.e. Cal Procedure,						
Repairs, Parts, etc., entered correctly into Labmate?		L	l			

Quality Manual

Correct	ve action/s by		
Tech:			
Tech Si	gnature:		
CDI:		Time Spent:	Date:
Follow-u	p action/s by		
QAR: _			
QAR: _		Time Spent:	
Date:			

<u>APPENDIX E</u>

Monthly Laboratory Quality Program Report Fax to Mark A. Kramer at; Comm (229) 639-6172, DSN 567-6172

Lab Code		Total Laboratory Calibrations:						
Month/Year	·- v	Total Final QVI's Completed:						
Proces	ss Audits	Final QVI's						
Item #	Total # of Non-	Item # Total # of N						
	Conformances		Conformances					
1.		1.						
2.		2.	***************************************					
3.		3.						
4.		4.						
5.		5.						
6.		6.						
7.		7.						
8.		8.						
9.		9.						
10.		10.						
11.		11.						
	1	12.						
		13.						
		14.						
		15.						
Instructions: Legib	ly complete and fax	to number above by th	e 5 th of the month or					
		d e-mail to kramerma@	matcom.usmc.mil					
QAR e-mail addres	s:	Phone #						
QAR:		Date:						

APPENDIX F

Calibration Customer Survey / Complaint Form

This form is to be completed by the customer. The responses are used as a guide to evaluate, and if possible, improve the processes at the Calibration Laboratory. The customer survey stops at the line of asterisks.

Customer:	Date:						
Unit/Ruc:	Phone:						
Service Provided	0 - N/A 1 - Poor 2 - Marginal 3 - Satisifactory 4 - Very Good 5 - Outstanding	Customer Remarks					
1. Ease of turning TMDE in for Calibration?							
2. Turn around time?							
3. TMDE functioning properly when received from Calibration?							
4. ERO and Calibration Labels Correct?							
Overall rating of quality of service.							
Remarks/Complaints							
Complaint received by:	***************	**************************************					
Corrective action taken by: Follow-up action taken by:							
Laboratory Calibration Chie	ef:	Date:					

APPENDIX G

METCAL QM Recommended Change From								
Fax completed form to: Metrology Quality Program Manager, Mr. Mark Kramer at, Fax no. Comm (229) 639-6172, DSN 567-6172.								
(This section is to be filled out by the individual requesting the docum	nent/engineering change)							
Name:	Date:							
Organization:	Phone:							
Recommended Change: (Identify page number/section ar separate sheet if needed for continuation.)	nd proposed rewrite. Use							
Reason for recommendation:								
This section is to be filled out by Quality Program Manager: Date: Document Control	ol Number:							
Incorporate recommendation at next Do not incorporate recommendation	t annual QM review							
Reason:	•							

APPENDIX H

USMC Metrology Supplier Certification Form

This certification form is part of our efforts to comply with DoD directives and to ensure that metrology service providers have documented and functioning quality systems that meet the requirements of the ANSI/NCSL Z540-1 or ISO Guide 25.

A certified supplier is one that has shown a complete and thorough understanding of our needs. In doing so the supplier has set in place a process that has been investigated and has been found to yield products or services that meet or exceed our requirements¹.

Please place a check under the appropriate column, or circle the most appropriate choice in applicable questions. The "on-site visit" questions at the end of some sections are applicable if and when a Marine Corps representative visits your site and will be completed by that representative.

1. QUALITY PROGRAM

Yes No.

<u>u, u, , , , , , , , , , , , , , , , , ,</u>	TETT THOUTH	163	140
	Does your calibration service have a quality program in place?		<u>-</u>
	What is the quality standard or specification for the quality program? Circle all that apply.		
	ISO 9001 or 9002 • ISO/IEC Guide 25 • ANSI/NCSL Z540-1		
П	Does your calibration service have a Quality Manager to oversee		
	the quality program and is the Quality Manager documented in the		
	company organizational chart?		
	If your calibration service is accredited, please send a copy of the		
	Accreditation Certificate with scope of measurement capabilities.		
	On-site visit;		
	Ask for internal audit results and completed in-process and final		
	inspection checklists. Do these documents demonstrate that the quality		
	program is followed IAW the documented quality program?		
MEA	ASUREMENT TRACEABILITY		
	Is your calibration service traceable to the National Institute of		
	Standards and Technology in all measurement areas?		
	Are all active standards currently calibrated?		
_	On-site visit;		
	Ask to see reports of calibration or other traceability records		
	of standards in use. Is there documented proof of traceability?		

¹James L. Bossert, Supplier Management, (ASQ Quality Press, 1994), p128

3.	<u>TRA</u>	NNING PROGRAM & TECHNICAL STAFF	Yes	<u>No</u>
		Is a well documented training program in place?		
		Does it cover both technical and clerical personnel?		
		Is there a training manual or folder for each staff member?		
		Is the technical staff regularly evaluated for current capability		
		in their areas of expertise?		
	_	On-site visit;		
		Does the laboratory have a large enough technical staff to service		
		your calibration needs (pertinent if you require a quick turnaround time)? Ask to see several training records. Do they demonstrate continuous		
	ш	and specific training for the types of employee work assignments?		
		and opening that the types of employee work assignments:		
4.	FAC	ELITIES/LABORATORIES		
		Is there a system to control and monitor environmental requirements?		
		Are documented laboratory operation procedures in place?		
		Are validated instrument calibration procedures implemented and		
		are they readily available to each technician?		
	لسنا	Is the calibration workload organized and tightly controlled? On-site visit;		
	\Box	Are documented laboratory operation procedures adhered to?		
	\Box	Are the facilities neat, clean and organized to promote reliable		
		calibration?		
		Is there a well-organized system of handling/processing customer		
		equipment?		
5.	CAL	IBRATION STANDARDS		
		Are calibration standards on a recall program?		
		Are the standards evaluated for compliance to customer or		
		original equipment manufacturer accuracy requirements?		
		Are the calibration standards evaluated to assure adequacy of		
		measurements?		
		Do the standards meet or exceed the 4:1 test accuracy principle?		
		Are measurement uncertainty issues addressed? Are reports of calibration available to technicians?		
		Are standards supported by accredited laboratories?		
		Are written calibration procedures approved before use and do they		
		reflect the standards used to conduct calibrations?		
		Are automated calibration procedures approved before use and do they		
		reflect the standards used to conduct calibrations?		
		On-site visit;		
		Is there documented evidence of a recalibration (recall program)?		
		Are reports of calibration maintained and available to technicians?		

6.	<u>MEA</u>	SUREMENT ASSURANCE	Yes	No
		Are calibration operations evaluated overall to assure compliance to measurement requirements? ie. Internal audits	15. 49 × ×	
		Are check standards utilized during the calibration process to assure accurate calibration?		
		On-site visit; Is there documented evidence of internal audits or other evaluations of		-
		calibration operations? Is there evidence of check standard usage?		
7.	CAL	IBRATION DATA MANAGEMENT		
		Are customers automatically notified via fax or mail in advance of items coming due for calibration?		
		Is there a data management security system in place to store and protect calibration data?		
		Is electronic data transfer available to the customer?	 ;	
		Does the content of calibration certs or reports conform to the Z540 or Guide 25?		
		Is the calibration data system capable of "reverse traceability" in the event of out-of-spec laboratory standards?		
		Are customers notified of items found out-of-tolerance during calibration and provided "as found, as left" data?		
	en de la companya de	On-site visit;		
		Ask to see data management system.		
		Is the data management system adequate?		
		Is the data management system organized?		
		Is the data management system up-to-date?		

8.

<u> </u>	TOMER SERVICES	<u>Yes</u>	<u>No</u>
	What type of warranty system for repair is in place?		
□ prior	Does your calibration service advise the customer of repair costs to repair?		
□ prior t	Does your calibration service obtain authorization from the customer to subcontracting equipment calibration? How long has your service been in business?		
ш	rion long has your corvice been in business:		
Name			
	e of person completing this form:		
Title _	e of person completing this form: Phone # Date: _		
Title _ Fax #	e of person completing this form:		
Title _ Fax # Marin	e of person completing this form: Phone # Date: _		

Please return the following items with this completed form to the Marine Corps Metrology Quality Manager;

- a. Copy of Quality Manual (software copy if available)
- b. Copy of the Accreditation Certificate (if applicable)
- c. Measurement capabilities
- d. Calibration data form returned with TMDE to customer
- e. Out-of-Tolerance form
- f. Non accredited laboratories; Provide names of three customer references including POC, title, and phone number for each reference.

Send to:

Maintenance Center

ATTN: Mark Kramer (Code 883) 814 Radford Blvd STE 20325 Albany, GA 31704-1128

E-mail: kramerma@matcom.usmc.mil

Phone # (229) 639-6049 Fax # (229) 639-6172

Note: Parts of this form were reproduced with permission by, K. W. Cable, Northwest Calibration Systems

APPENDIX I

Calibration Service Provider Discrepancy Form

S	Service Provider Name:	Name:	Date Discrepancy Discovered:	ë
Item #	Barcode #	S/N	Discrepancy	Remarks
-				
2.				
3.				
4				
5.				
.9				
7.				
Signatur	Signature of FMF QAR or Cal Chief:	Cal Chief:	Phone #	
Fax to: C	⊋uality Manager a	t DSN 567-6172 (Commerc	Fax to: Quality Manager at DSN 567-6172 (Commercial 229-639-6172) or E-mail completed form to kramerma@matcom.usmc.mil	erma@matcom.usmc.mil
Service	Service Provider POC		Phone #	
Correctiv	Corrective Action			
Date Col	Date Corrective action complete:	nplete:	QAR or Cal Chief Satisfaction Signature	

APPENDIX J

OJT Documentation Form

								•					
7	4TH ITEM	Date:	Model:	Senior Tech:			O NOT A GOIL	CALIBRA HON CHIEF:	×		TO MACHINE OF VEHICLE	REPRESENTITIVE:	×
	3RD ITEM	Date:	Model:	Senior Tech:		10TH ITEM	<u>Date:</u>	Model:	Senior Tech:	15TH ITEM	Date:	Model:	Quality Assurance:
Measurement Area:	2ND ITEM	<u>Date:</u>	Model:	Senior Tech:		9TH ITEM	<u>Date:</u>	<u>Model:</u>	Senior Tech:	14TH ITEM	Date:	Model:	Quality Assurance:
	1ST ITEM	<u>Date:</u>	<u>Model:</u>	Senior Tech:		8TH ITEM	<u>Date:</u>	Model:	Senior Tech:	13TH ITEM	Date:	Model:	Quality Assurance:
hnician:	 NO	ite				7TH ITEM	<u>Date:</u>	Model:	Senior Tech:	12TH ITEM	Date:	Model:	Quality Assurance:
Apprentice Technician:	CLASSROOM TYPE INSTRUCTION	Hours Date			DER: x	<u>бтн ітем</u>	<u>Date:</u>	Model:	Senior Tech:	11TH ITEM (100% Inspection)	Date:	Model:	Quality Assurance:
LAB:	CLASSR		Review TM /s Review ICP /s	Review Test Equipment	INSTRUCTION PROVIDER: x	5TH ITEM	<u>Date:</u>	Model:	Senior Tech:	<u>QA USE</u>			

OJT OVERVIEW: Prior to performing calibrations, technicians receive the appropriate training to ensure a thorough comprehension of laboratory tests. OJT will not supplant formal Metrology training and may be utilized on a case-by-case basis to meet mission requirements. In the absence of formal school training, or as a continuation to introduction level formal training, this OJT form documents the efforts of the laboratory in providing that training, guidance, observations and verifications. The Calibration Chief has overall OJT responsibility.

OJT INSTRUCTIONS: Classroom training may be as simple as a Senior technician reviewing and explaining the technical manual or calibration procedure to the apprentice technician. The Senior technician provides calibration guidance while observing the apprentice for ten items. Data is recorded. The Calibration Chief attests by signature that the technician is competent to perform calibrations within the specific measurement area and scope of documented training.

QUALITY ASSURANCE: The Calibration Chief notifies the Quality Assurance Representative (QAR) when the technician has demonstrated proficiency. The QAR inspects and documents up to five calibrations. The first calibration inspection is a one hundred percent "over the shoulder" inspection with up to the next four calibrations receiving an In-Process inspection.